



KGI BIOHAZARDOUS WASTE MANAGEMENT PLAN

I. Facility Information

a. **Contact Person:** Jasmine Yu, Laboratory Safety Manager, Office Phone 909- 607-8698

i. **Facility:** Keck Graduate Institute of Applied Life Sciences

535 Watson Drive

Claremont Ca, 91711

Phone: (909) 607-0144

b. **Type of Facility:** Academic Institution (Classrooms and Laboratories)

c. **Types of waste and monthly average generated:** Bacterial samples, Biological Safety level 2, and average waste monthly \leq 200 lbs. There is no medical waste generated at this site, only biological waste.

d. **On site Biological Waste treatment:** Two (2) Autoclave steam sterilization units; Steris Amsco model 3023. One located in building 517 SN: R831911001, and one in building 535 SN:R831591208.

e. **No waste hauler used**

f. **No offsite treatment used.**

g. **Emergency Action Plan:** KGI has two autoclaves one will provide backup service to the other. If material needs to be transported between the two autoclaves it will be secured by using Velcro earthquake straps during transport. If both autoclaves go down a certified Biological Waste Management company will be used to dispose of waste.

h. **In the case of a natural disaster,** such as, an earthquake that can potentially cause equipment failure the unit(s) would be shut down/out of service until a professional service provider can inspect the unit(s) and perform the recommended service (i.e. re-calibration, parts, leakage, etc.) before the unit(s) can be re-started for use again.

i. **The above information is complete and correct to the best of my knowledge:**

i. Spencer La Placa on behalf of KGI _____

j. **Biological Waste Tracking Documents** see attached Documents 1 and 2.

k. **No medical waste, biological samples only.**

l. **No medical waste will be produced consisting of human anatomical remains, radiological materials, or chemotherapeutic.**

m. **Pharmaceutical waste is generated by pharmaceutical compounding lab once a year.**

There are three weeks of Pharmaceutical compounding lab each year. Students learn to make tablets, capsules, ointment, cream, and other drug formula. All compounding products and left over materials are collected in special pharmaceutical waste containers and picked up by North

State Environmental.

II. **Containment and Storage Information.**

a. **Infectious, Potentially Infectious, or R-DNA Biological Waste**

- i. any material containing or contaminated with **human pathogens**
- ii. any material containing or contaminated with **animal pathogens**
- iii. any material containing or contaminated with **recombinant DNA or recombinant organisms**
- iv. laboratory and clinical wastes containing **human blood products, tissue, cell cultures, and other potentially infectious material (OPIM)**
- v. Used, absorbent materials contaminated with blood products, or OPIM
- vi. Non-absorbent, disposable devices that have been contaminated with blood, body fluids or OPIM
- vii. **Biohazard Liners:** Red biohazard liners are to be tied to prevent leakage or expulsion of contents during all future storage, handling, and transport.
- viii. Red biohazard bags are to be placed for storage, handling, and transport in rigid containers with tight-fitting lids labeled with the words "Biohazardous Waste", or the word "Biohazard" and the international biohazard symbol on the lids and sides so as to be visible from any lateral direction.
- ix. Rigid containers that hold waste shall be decontaminated by 10% bleach or by Cavicide disinfecting wipes at least once every 7 days.
- x. **Medical Related Spills:** See appropriate lab protocols for proper procedure(s) on cleaning.

b. **Laboratory waste containing infectious, potentially infectious, or rDNA must be inactivated prior to leaving the facility.**

- i. The preferred method is steam sterilization (autoclaving), although inactivation (e.g. treatment with household bleach) may be appropriate in some cases.
- ii. Storage of all non-inactivated waste in this category is restricted to within the generating laboratory. Infectious or pathogenic waste must be held in a closed/covered biohazard waste container and may not be stored longer than 7 days prior to inactivation.
- iii. Biological waste containers and bags for material that is infectious/potentially infectious to humans must be labeled with the biohazard symbol.
- iv. . Filled or partially filled biological waste containers and boxes should not be held for more than 7 days at temperatures above 32°F or 0°C.

III. **Biological Waste Packing, Labeling, & Transport:**

a. **Discharge to the public sewer system**

- i. As a general rule, add household bleach to a final concentration of 10%, wait 10 minutes or until dry, then rinse down the sink with copious amounts of water.
- ii. Alternatively, a disinfectant that is known to be effective against the organism may be added to an appropriate concentration, Per the manufacturers recommendations, the wait kill time will be determined, then rinse down the sink with copious amounts of water.

IV. **Steam Sterilization**

a. **Factors in autoclave function**

- i. **Steam:** The energetics of steam makes it far more efficient for sterilization and decontamination than dry heat at the same temperature. Effective steam sterilization depends on the interaction of temperature, pressure, and time, but additional conditions inside the autoclave chamber such as materials, containers, container placement, and total volume of the materials also influence sterilization success. Each of these factors must be controlled within a narrow range of values or conditions:
- ii. **Pressure/temperature relationship:** Pressurization to 15 psi typically "superheats" steam to about 121°C (250°F), which is adequate to kill all microorganisms and to decontaminate or sterilize in reasonable time.
- iii. **Time:** Other factors being equal, autoclave loads up to about 2.0 ft³ in volume require 30-60 minutes to sterilize at 15 psi and 121°C. Larger loads and tightly packed materials require 60 minutes.
- iv. **Contact:** To sterilize or decontaminate uniformly, superheated steam must contact all areas of the load. To ensure steam can reach the center of biohazard waste load, biohazard waste bags should be kept open during inactivation. If the waste is dry solid, some water may be added to the bag before autoclaving.
- v. **Volume:** "Dense" materials such as media in bottles to be treated in the autoclave should occupy **no more than half** of the autoclave chamber volume, so that steam can circulate completely around and into the load. Less dense materials such as bagged waste can occupy somewhat more space but should never contact the autoclave chamber wall.
- vi. **Dry heat:** Some autoclaves offer dry heat cycles, which are useful for sterilizing laboratory supplies such as Kim Wipes that can withstand high temperatures but would be damaged by steam. The necessary exposure times for dry heat vary considerably depending on materials composition, packaging, load volume, and possibly other factors, and may be more than triple the time needed for steam sterilization at the same temperature. Because the required times for successful dry heat sterilization vary so much the user may need to experiment extensively with appropriate times and temperatures to develop a consistently successful dry heat sterilization protocol.

b. **Container Selection**

- i. **Bio-waste Containers**
 1. Sturdy, red bio-waste cans displaying the biohazard sign are used as the terminal receptacle. Line the can with approved ASTM Biohazardous red liner of appropriate size.
 2. Do not overfill (<2/3 full), or cause the lid of the can to stand open to waste.
 3. Do not keep bio-waste for more than 7 days.
- ii. **Sharps Containers**
 1. Before disposal, Label with date, PI name, room number, and telephone number.
 2. Tape all seams to prevent lids from accidentally opening.
 3. Close when ¾ full and place in waste pickup for disposal. Sharps containers are picked up by North State every three months.
- iii. **Polypropylene bags.** According to the Medical Waste Management Act (MWMA) "(b) the biohazard liner that is used to collect medical waste within a facility shall be manufacturer certified to meet the ASTM D1709 dart drop test and D1922, Tear Resistance. The color of the bag shall be red. The biohazard bag shall be marked with the international biohazard symbol.
- iv. **Place liners in a rigid container during autoclaving.** Liners are available in a variety of sizes, and some are printed with an indicator that changes color when processed.
 1. Do not put liquids into the liners. Label with date, PI name, room number, and

- telephone number.
2. Red biohazard liners are placed in a black trash bag with a label on outside indicating (decontaminated, date, PI name, and lab number) for disposal.
 3. Polypropylene liners are impermeable to steam, and for this reason should not be twisted and taped shut, but **opened loosely at the top**. This will create an opening through which steam can penetrate.
- v. **Polypropylene containers and pans.** Polypropylene is a plastic capable of withstanding autoclaving, but resistant to heat transfer. Therefore, materials contained in a polypropylene pan will take longer to autoclave than the same materials in a stainless steel pan. To decrease the time required to sterilize material in these containers,
1. Remove the lid (if applicable).
 2. Turn the container on its side when possible.
 3. Select the container with the lowest sides and widest diameter possible for the autoclave.
 4. **90 min** is required to completely inactivate biohazard waste if using polypropylene pan.
- vi. **Stainless steel containers and pans.** Stainless steel is a good conductor of heat and is less likely to increase sterilizing time, though is more expensive than polypropylene. If autoclaving in stainless steel pan, **60 min** is sufficient to inactivate biohazard waste.
- vii. **Preparation and Loading of Materials**
1. Fill liquid containers only half full.
 2. Loosen caps or use vented closures.
 3. Always put bags of biological waste into pans to catch spills.
 4. Position biohazard bags on their sides, with the bag neck taped loosely.
 5. Leave space between items to allow steam circulation.
 6. Household dishpans melt in the autoclave. Use autoclavable polypropylene or stainless steel pans.
- viii. **Cycle Monitoring**
1. Both autoclaves are equipped with a chart recorder to record, temperatures, pressure and run times. Please look at each tape when run is complete to ensure that the run was successful.
- ix. **Cycle Selection**
1. Use liquid cycle (slow exhaust) when autoclaving liquids, to prevent contents from boiling over.
 - a. Select fast exhaust cycle for glassware.
 - b. Use fast exhaust and dry cycle for wrapped items.
- x. **Time Selection**
1. Take into account the size of the articles to be autoclaved. A 2-liter flask containing 1 liter of liquid takes longer to sterilize than four 500 mL flasks each containing 250 mL of liquid.
 2. Material with a high insulating capacity (high sided polypropylene containers) increases the time needed for the load to reach sterilizing temperatures.
 3. Autoclave bags containing biological waste should be autoclaved for 60 minutes in plastic pan or 60 min in stainless steel pan with the bag open to assure decontamination.
- xi. **Removing the Load (Approved PPE Required)**
1. Check that the chamber pressure is zero.
 2. Wear lab coat, eye protection, heat insulating gloves, and closed-toe shoes.
 3. Stand behind door when opening it.
 4. Slowly open door only a crack. Beware of rush of steam.
 5. After the slow exhaust cycle, open autoclave door and allow liquids to cool for 20

minutes before removing.

- xii. **Service:** A professionally trained service provider will inspect the autoclave according to the autoclave manufacturer's recommendations for inspection intervals and service. Most such recommendations are based on cumulative hours of use rather than specific calendar intervals. Autoclave gauges will be calibrated at least annually. If an autoclave fails to function correctly or a user finds a problem between scheduled inspections, the unit must be professionally serviced. **Do not resume operation of an autoclave until it has been inspected and repaired. call Jasmine Yu at x78698**

a. **Testing Autoclaves for Effectiveness**

- i. Autoclaves used for pathogen kill-loads or clean glassware sterilizing cycles, should be routinely tested once per month for killing effectiveness. Before placing new autoclaves into service, killing effectiveness testing must be completed.
- ii. The method of testing is using commercially available test indicator kits with spore strips (usually *Bacillus stearothermophilus*). We use protest self-contained biological indicator from Mesa Labs.
- iii. The spore test kit are placed in the center of a typical load and run through a sterilization cycle for 60-90 minutes depending on the size of load and autoclave pan to use.
- iv. The spore strips are incubated with the non-autoclaved strips as negative control.
- v. To remove the spore strips from the biohazard bag without exposure to the contents, place the fresh spore strips inside of an small autoclave envelop.
- vi. If growth is noted on the autoclaved spore strips call **Jasmine Yu at x78698**.
- vii. Autoclaves will be tested before being placed into service, and then retested monthly for effectiveness.

b. **Method of Testing**

- i. A commercially available test indicator kit that uses bacterial spores (*Bacillus stearothermophilus*) is the approved method of testing autoclave efficiency. Most spore vial test kits require 56 to 60 ° C incubation of the autoclaved test vial along with a non-autoclaved control vial for 24 hours. Incubation causes surviving spores to grow, which validates the test.
- ii. New autoclaves before placing an autoclave into service, a test load approximating the weight and density of the type of waste generated shall be autoclaved with test spore vials. The spore vial should be placed in the middle of the waste inside the bag. This can be achieved by either:
 1. placing the vial at the position within one large test load, OR
 2. The appropriate parameters for sterilization including temperature, pressure, and treatment time shall be determined in this way.
- iii. Autoclaves already in use: **Monthly** testing will be done by placing a spore vial in the very center of a biohazard waste load and keeping the liner open prior to autoclaving.
- iv. Spore Test Storage Information: Please read the spore vial product information sheet for appropriate storage information, but, in general, spore vials should not be refrigerated. Each batch of vials has an expiration date. Vials should not be used after their expiration date.

c. **Recordkeeping :** The following records regarding autoclave use must be kept for a minimum **three** years before disposal:

- i. On-site maintenance records
 1. Autoclave use log (Each load of material inactivated shall be logged as follows:
 - a. Date, time, and operator's name
 - b. Type and approximate amount of waste
 2. Confirmation of sterilization
 - a. Record the temperature, pressure, and length of time the load is sterilized.

Please note that temperature sensitive autoclave tape is not sufficient to indicate that the load reached sterilization conditions because the tape will change color at lower temperatures, OR Save the autoclave print-out.

3. A written sterilization procedure shall be in place for each workplace. This shall include the following:
 - a. Parameters
 - i. Appropriate parameters for sterilization shall be determined from the testing with spore vials.
 - ii. The time it takes to sterilize a load will change, depending upon the load density and the sterilization cycle one chooses. Therefore, tests should be performed which imitate these various situations.
 - a. Cleaning
 - i. The autoclave and work areas shall be cleaned after every use and the work area shall be disinfected as needed

d. **Transport**

- i. Transport biohazardous waste outside of the lab (i.e. to an autoclave) in a **closed, leak-proof** bag or container; bags must be contained in a leak proof tray.
- ii. Do not leave non-inactivated waste unattended.
- iii. Containers must be labeled on front side and the top with a biohazard sticker.
- iv. Outside hauler is used for sharps pickup. North-State Environmental is the outside hauler used to pick up and discard the sharps refuse. North-State Environmental company info:
[Address:](#) 1045 W Rialto Ave, Rialto, CA 92376
[Phone:](#) (909) 875-9288

V. **Training**

- a. All employees who handle biological waste shall be trained regarding the proper segregation, handling, packaging, labeling, storage, and treatment of biological waste. Refresher training is required annually.
- b. Records of the training session shall be maintained by the lab PI for each employee, along with an outline of the training program. Training records shall be retained for a period of three (3) years.

VI. **Disinfecting Techniques**

- a. Before leaving the BSL 2 area all sample carriers will be wiped down with Cavicide and/or 8% Vesphene and will sit twenty minutes prior to transport. 10% bleach may also be used, or 70% ethanol depending on samples being used.
- b. All work surfaces and any spills of the material will be decontaminated by treatment with a microbicide (e.g. 8% Vesphene, undiluted Cavicide, or similar) for 20 minutes. 10% bleach may also be used, or 70% ethanol depending on samples being used.
- c. All remaining liquid will be collected by paper towels and autoclaved.
- d. All autoclaved materials will be disposed of at the landfill.

VII. **Deploy Spill Cart in the need of spill contamination**

VIII. **Appendix A and B autoclave log sheets**
(see attached sheets)

IX. **Biohazardous Liner Specifications**